

POSTSCRIPTS

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POSTSCRIPTS

AIMS AND SCOPE

Postscripts is the newsmagazine of the American Medical Writers Association Pacific-Southwest (AMWA Pac-SW) chapter. It publishes news, notices and authoritative articles of interest in all areas of medical and scientific writing and communications. The scope covers clinical/regulatory writing, scientific writing, publication planning, social media, current regulations, ethical issues, and good writing techniques.

MISSION STATEMENT

The mission of *Postscripts* is to facilitate the professional development of medical writers and serve as a tool to advance networking and mentoring opportunities among all members. Towards this mission, *Postscripts* publishes significant advances in issues, regulations and practice of medical writing and communications; skills and language; summaries and reports of meetings and symposia; book and journal summaries. Additionally, to promote career and networking needs of the members, *Postscripts* includes news and event notices covering Chapter activities.

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INSTRUCTION FOR CONTRIBUTORS

We welcome contributions from members and non-members alike.
Please contact editor.

ADVERTISING

Articles describing products and services relevant to medical writers may be considered or solicited. Members may submit advertisements for their services or products for free. Please contact editor for details.

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POSTSCRIPTS

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CHAPTER EVENTS AND NOTICES

- **December 10th:** AMWA National webinar – Donna Simcoe will be presenting about Publication Planning
- **December 12th:** Free chapter webinar about Patient Communication held jointly with the San Diego Clinical Research Network (SDCRN). Flyer will be sent soon.
- **January 24th:** 50th Anniversary Celebration!! We are planning to hold this event in LA. More details forthcoming. Please Save the Date to celebrate all of our great accomplishments over the past 50 years!
- **May 1 – May 2, 2015:** *****SAVE THE DATE***** **2015 AMWA Pac-SW Conference**, Courtyard Marriott San Diego.

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From the President's Desk

“Let us be grateful to people who make us happy; they are the charming gardeners who make our souls blossom.” — Marcel Proust

Hello all,

Now that we are in November, I am thankful to have met many of you at the AMWA annual meeting in Memphis, including some of our new members. We were delighted that 45 of our chapter members could join us at the annual greet-and-go dinner (see pictures in this newsletter). A fun time was had by all! And great news, the AMWA National Board passed our updated chapter bylaws!

In this newsletter, Rebecca Anderson makes us laugh by summarizing the Ig Nobel awards. We have a summary of manuscript disclosure, transparency and financial conflicts of interest by Dikran Toroser, updates at the FDA and the EMA written by Amanda Fisher and Wlm D’Haeze, respectively, and how to navigate the navigation pane by Susan Chang. We thank our Arizona chapter delegate, Kathy Boltz, and our Newsletter Editor, Ajay Malik, for their fun summaries about Memphis.

Please join me in giving heartfelt thanks to a few of our chapter supporters who will be stepping down. We thank our Employment Coordinator, Irene Yau, for the wonderful ‘job’ she does at keeping us updated about job postings in our region, Mimi Wessling for all of her help with our chapter website (www.amwa-pacsw.org) and Jennifer Cossrow for keeping our Linked site updated (https://www.linkedin.com/groups?home=&gid=3857774&trk=anet_ug_hm). Thank you all for your significant contributions to our chapter!

With this transition, please allow me introduce 2 new members of our Chapter leadership and our open position. Welcome Laura and Andrew!

- Website Coordinator: Laura J Cobb, PhD (we are planning to revamp our website so stay tuned)
- Chapter Secretary: Andrew Hellman, PhD (now helping on multiple fronts including updating LinkedIn)
- Employment Coordinator: This is now an open position. If anyone is interested in being our new Employment Coordinator and helping to keep the membership updated about jobs in our region, please email me. This is a great way to network and stay abreast of who is hiring in our region.

Since our chapter is so widely spread geographically (our members extend from Santa Barbara into southern California and also into Nevada and Arizona), we are trying to connect more with our members online. If anyone is interested in giving a talk over webinar or trying a Google Hangout with other medical writers, please contact us. If you wish to contribute to our newsletter, please contact our star Newsletter Editor, Ajay Malik (ajay@amwa-pacsw.org).

Happy Thanksgiving!
Donna

Donna Simcoe, MS, MS, MBA, CMPP
President, AMWA Pacific Southwest Chapter



*AMWA Pacific-Southwest Chapter warmly
welcomes our new members*

Amy Van Gels - Gilbert, AZ

Ken Landow - Las Vegas, NV

Melissa Meister - Las Vegas, NV

Paul Kostenuik - Newbury Park, CA

Philip Babig - Newbury Park, CA

List courtesy of Gail Flores, PhD, AMWA-PacSW membership coordinator.

Reminiscing Memphis

Last month about 700 medical communicators, including medical writers, publication professionals, designers and other AMWA members from all over North America headed to Memphis for the 74th AMWA Annual Conference. They came to Memphis for what the New York Times bestseller author James Dashner once said: "Write each and every day if possible — then try to attend professional writer's conferences where you can learn your craft, get to know fellow writers."¹

At the AMWA conference, there were 60 workshops, 48 open sessions, 75 roundtables, and 3 keynote addresses to choose from—there was something for everybody at the conference. The conference was a **"Resource for Medical Writers"** just as the AMWA's brand message says.

The workshops were designed to make us feel like a kid again with a classroom teaching environment and the excitement of learning something new. These workshops have long served as the primary reason for most writers to attend the AMWA meetings. They were half-day interactive exercises and participation counted towards 1 of 4 AMWA certificates: (1) essential skills, (2) composition and publication, (3) regulatory and research, and (4) concepts in medicine and science.

On the flip side, choosing to attend 3 or more workshops meant that you could not attend most open sessions. (Unfortunately, we can't have everything we want.) But those who managed their schedule were rewarded with a wide variety of topics and discussions in open sessions.

Open Sessions

The open sessions along with roundtables could be considered as sandboxes where new ideas and topics germinate and became the focus of discussion. There were staples (topics), such as, sharing experiences in leadership; managing projects, teams and clients; work-life balance, freelance career, and soft skills. Also discussed



were interesting new and popular topics, such as, CTD pyramid, development and implementation of ICH guidelines, AuthorAID, Sunshine Act, setting up webinars, managing a QC workflow, managing brochure design and publishing, and so on. In fact, it was really difficult to choose which session to attend and which to skip—it was not that different from a kid given permission to pick only 3 candies from his large Halloween loot. For us, though, it is not all lost: Check out the list of presenters from our Chapter on Page 192. These fellow members are our post-conference resources.

Keynote Presentations

Even if you decided to skip all sessions and head to Graceland to pay homage to the King or preferred soaking in the Blues at Beale Street in Memphis downtown, it's hard to believe that you might have missed the keynote addresses by Gary Schwitzer and Rosemary Gibson, who were awarded the McGovern Medal and Alvarez Award, respectively. Both have spent their professional lives empowering healthcare consumers by stripping hype from drug messages, fostering debate in the way healthcare is delivered, and promoting patient safety.

Gary Schwitzer

Gary Schwitzer, publisher of HealthNewsReview.org, has graded health news reporting by major news outlets, professional organizations and even medical journals for the last 8 years. He started his talk with a Yogi Berra quote: "If you come to a fork in the road, take it," in fact, this is what the healthcare consumers do when they come to a website: they read it, believe

it, and make decisions based on the information on those web reports and news. Unfortunately, so much of health reporting is not only bad but also dangerous. Gary has published 8 tests that he applies to all health news and reports to separate bad and biased reporting from unbiased reports.²

The HealthNewsReview.org lists the following tests that his team uses to grade the medical news stories:

- What's the total cost?
- How often do benefits occur?
- How often do harms occur?
- How strong is the evidence?
- Is this condition exaggerated?
- Are there alternative options?
- Is this really a new approach?
- Is it available to me?
- Who's promoting this?
- Do they have a conflict of interest?

As medical writers, when we are reading healthcare news stories, Gary suggests, we should also subject these stories to the litmus tests (above). Or when we are writing, we need to be mindful of these issues. This is increasingly important in the current environment where increasingly the news stories are based on weak evidence (based on surrogate endpoints and observational studies) and there is a pressure to be the first to present breakthrough stories—the word “*breakthrough*” itself is often misused when based on data from experimental animal studies or preliminary Phase 1 clinical testing.

Rosemary Gibson

While the AMWA conference started with Gary's address, it ended with the presentation by Rosemary Gibson, MSc, on her work promoting the quality of healthcare and promoting dialog in the healthcare delivery model in the US.

Rosemary said during her presentation: “When you are writing at 44,000 feet, always think what's happening at 3 feet—that's my moral compass, has been, will be.” Going back 16 years when she worked in palliative care at Robert Wood Johnson Foundation, NJ, she said that she came across a

book in the RWJF library. It was a report by Institute of Medicine, “To Err is Human” which talked about errors in healthcare (errors because we often don't get it right), and while other industries had become safer, the healthcare industry had lagged behind. Rosemary was deeply influenced by this book, and she said that she had marked it so badly that she never took it back to the library. Over the years, she went on to interview people who had been at the receiving end of healthcare. Their stories over the last decade have culminated in several influential books.

Her first book, “Wall of Silence” is a story of a mother whose son died of complications after a routine tonsillectomy. The focus on patient safety, new protocols in hospitals, and impetus to minimise hospital-acquired infections is a legacy of this book. Another book, “Treatment Trap” takes up the issue of “harm from overuse” from healthcare procedures. Two other books, “Battle Over Healthcare” and “Medicare Meltdown” not only draw parallels to the stock market bubbles and toxic assets with the current economics of healthcare, but also talk about ideological politics as one of the monkey wrenches in the debate over healthcare reforms. There are other big elephants in the room that we will have to confront soon, including a disproportionate amount of money spent on end of life, as mentioned during Q&A.

She said that her research/resource for her stories is “listening to people.” Her talk's title, “Becoming a Medical Writer: The Journey and the Destination,” sums how she became a medical writer, an advocate, a health policy expert, and a voice of reason in the middle of an often cantankerous healthcare debate in political circles. She is currently a Senior Advisor to The Hastings Center and is Section Editor for the *Less is More Perspectives* series in JAMA Internal Medicine.

—Ajay K Malik, PhD

¹ James DashnerQuote. <http://www.brainyquote.com/quotes/quotes/j/jamesdashn537377.html>

² Schwitzer G. A Guide to Reading Health Care News Stories. JAMA Intern Med. 2014;174(7):1183-1186.

The Ig Nobel Awards — 2014 Edition

By Rebecca J. Anderson, PhD

As you probably know, the Nobel Prize winners for 2014 were announced last month, and the winners will pick up their medals and cash at ceremonies in Norway and Sweden next month. Like matter and anti-matter (to use a scientific analogy), the Nobel Prizes always trigger their counterpart, the Ig Nobel Prizes. Each year, the editors of the *Annals of Improbable Research* recognize “achievements that make people laugh and then make them think.” To add credence to the Ig Nobel ceremony, which is held at Harvard University, the awards are presented by genuine Nobel Laureates. The Ig Nobel winners for 2014 lived up to the proud tradition and high expectations of the Ig Nobel founders and organizers.

Below are some of the highlights (and see pictures on the next page):

Physics Prize: A Japanese team won for measuring the amount of friction between a shoe and a banana skin, and between a banana skin and the floor, when a person steps on a banana. These researchers discovered that the banana’s polysaccharide follicular gel was an industrial-grade lubricant. Guess what! They’ve “stumbled upon” a renewable petroleum substitute.

Psychology Prize: Collaborators from the UK, US, and Australia won for amassing evidence that people who habitually stay up late are, on average, more self-admiring, more manipulative, and more psychopathic than people who habitually rise early in the morning. Nite owls, beware!

Public Health Prize: Researchers from the Czech Republic, Japan, US, and India collaborated to investigate whether it is mentally hazardous for a human being to own a cat. (If you own a cat, you already know.)

Biology Prize: Top honors were awarded to a multi-national team of researchers for carefully documenting that dogs tend to align their bodies with Earth’s north-south geomagnetic field when they do their business. They published their

results in *Frontiers in Zoology*. How appropriate is that?

Art Prize: An Italian team won for measuring the relative pain people suffered (when being shot in the hand by a powerful laser beam) while looking at an ugly painting versus a pretty painting. Beautiful paintings made the subjects less sensitive to pain while ugly paintings lowered their pain threshold—a tip to keep in mind when you’re selecting your boss’s next holiday gift.

Economics Prize: This year’s winner was the Italian government’s National Institute of Statistics for taking the lead in fulfilling the European Union’s mandate to increase the official size of each EU country’s economy. In a stroke of genius, the Italian statisticians captured the revenues from prostitution, illegal drug sales, smuggling, and all other unlawful financial transactions between willing participants. *La dolce vita!*

Medicine Prize: Scientists in the US and India collaborated in reporting that you can treat “uncontrollable” nosebleeds by packing the nose with strips of cured pork. (I don’t know what you do if you’re a vegan.)

And finally, the **Nutrition Prize** went to a Spanish team for their study entitled, “Characterization of Lactic Acid Bacteria Isolated from Infant Feces as Potential Probiotic Starter Cultures for Fermented Sausages.” Perhaps these researchers were inspired by kopi luwak, the super-expensive capPOOcino that is made from coffee beans that have passed through the digestive system of the palm civet, a Southeast Asian cat-like animal.

Further details, a complete list of winners, and videos of this year’s ceremony can be found on the Improbable Research website, www.improbable.com.

(Rebecca can be reached at rebeccanderson@msn.com)

Explaining banana peel experiment



Demonstration of how pain threshold changes while looking at a painting



The strips of cured pork designed to pack the nose

Nasal Packing With Strips of Cured Pork as Treatment for Uncontrollable Epistaxis in a Patient With Glanzmann Thrombasthenia

Ian Humphreys, DO; Sonal Saraiya, MD; Walter Belenky, MD; James Dworkin, PhD

Objectives: Glanzmann Thrombasthenia, platelet dysfunction, agents, and blood products, and embolism



Cured, salted pork was cut into strips approximately 3.5 x 0.5 x 0.5 cm and secured with 2-0 silk suture.

Demonstrating how dogs align with the geomagnetic field



Demonstrating how to isolate lactic acid bacteria from an infant and use as the probiotic starter for sausages



AMA-zing Style — the AMA Manual of Style Column

Dikran Toroser, PhD, CMPP, Amgen Inc.

Disclosure, Transparency and Financial Conflicts of Interest

Physicians and hospitals have a long history of productive collaboration with the pharmaceutical and medical device industries. While these relationships have helped advance new developments in health care, they have also raised issues of potential or perceived conflicts of interest—sparking an increased focus on transparency in these relationships.

“A conflict of interest is a set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest.”¹

A recent US legislation known as the “Sunshine Act” is intended to provide greater transparency into the relationships between pharmaceutical and device manufacturers and healthcare providers by disclosing “transfers of value.”² This is done through annual data collection from industry and release of disclosure information on a publicly-accessible website OpenPaymentsData.CMS.gov maintained by the CMS.

Medical communicators have responded positively to the calls for greater transparency and disclosure of industry-healthcare provider relationships.

The American Medical Association (AMA) policy² on Sunshine Act reporting states:

“. . . the AMA believes that physicians' relationships with industry should always be transparent, meaningfully independent, and focused on benefits to patients. This includes providing information physicians and the public need to make informed, critical judgments about interactions with industry and taking steps to ensure that physicians' clinical judgments are objective and evidence based. AMA policy also endorses transparency and independence.”

When and How Does Conflict of Interest Occur?

A conflict of interest may occur when an individual's objectivity is potentially compromised by a desire for financial gain, prominence, professional advancement, or a successful outcome. Conflicts of interest that arise from personal or financial relationships, academic competition, and intellectual passion are not uncommon in life—science is not an exception.

In a peer-reviewed publication, a conflict of interest may exist when an author has financial or other relationships that could influence (or bias) the author's decisions and work. However, much concern has been directed toward the financial interests of researchers and authors, perhaps because such interests can be measured, and because of the complex relationships between them and the funders of the work. In addition, concerns have increased about author biases associated with financial ties to industry and pressures from commercial influence.

Editors strive to ensure that manuscripts are balanced, objective, and as evidence-based as possible. Because of the difficulty in distinguishing the difference between an actual and perceived conflict of interest, many biomedical journals require authors to disclose

all relevant and potential conflicts of interest. Financial interests may include but are not limited to employment, consultancies, stock ownership, honoraria, expert testimony, royalties, patents (filed, pending, or registered), grants, and material or financial support from industry, government, or private agencies. Nonfinancial interests include personal or professional relationships, affiliations, knowledge, or beliefs that might affect objectivity.

History

In the 1980s biomedical journals began to require authors to disclose any financial interests in the subject of their manuscript. During the next 20 years, authors typically included information about financial support from grant and funding agencies in their submitted manuscripts, primarily because the funding agencies require them to do so, but it was less common for authors to disclose other financial interests, unless such information had been specifically requested.

Editors and Journals Supporting Full Disclosure Principles

Until recently, many journals did not have conflict of interest policies. All of the top-ranked general medical and multidisciplinary science journals now have such policies. Many biomedical journals, including *JAMA* and the *Archives Journals*, require disclosure of financial interest from everyone involved in the editorial process: authors, reviewers, editorial board members, and editors. The International Committee of Medical Journal Editors (ICMJE) and the Council of Science Editors (CSE) support this policy. Many journals also require individuals (such as editorial and publishing employees and full-time and part-time editors) who have access to material during the review and publication processes to comply with policies on conflicts of interest.

Requirements for Authors

Authors should disclose all relevant conflicts of interest in their work at the time of

manuscript submission either in the manuscript (if so required by the journal) or in a cover letter to the editor or on the journal's disclosure form (if the journal uses one).

JAMA authors are expected to provide detailed information about any relevant financial interests or financial conflicts within the past 5 years and for the foreseeable future. This includes financial involvement with a product or service that is in direct competition with a product or service described in the manuscript. *JAMA* and the *Archives Journals* require complete disclosure of all relevant financial relationships and potential financial conflicts of interest, regardless of amount or value.

Reporting Funding and Other Support

In addition to individual financial conflicts of interest, authors should report all financial and material support for the work reported in the manuscript. This includes grant support and funding, provision of equipment and supplies, and other paid contributions. All financial and material support should be indicated in the Acknowledgment section of the manuscript, along with detailed information on the roles of each funding source or sponsor. Also, all individuals who provided other important paid contributions should be identified. These contributions include the work of employed or compensated writers, editors, statisticians, epidemiologists, and others involved with manuscript preparation, data management, and analyses.

Reporting the Role of the Sponsor

In the interest of full disclosure, the ICMJE recommends that authors report how sponsors/funders have participated in the work reported in a specific manuscript. Journals should require authors to indicate the role of the sponsor/funding organization in each of the following: "design and conduct of

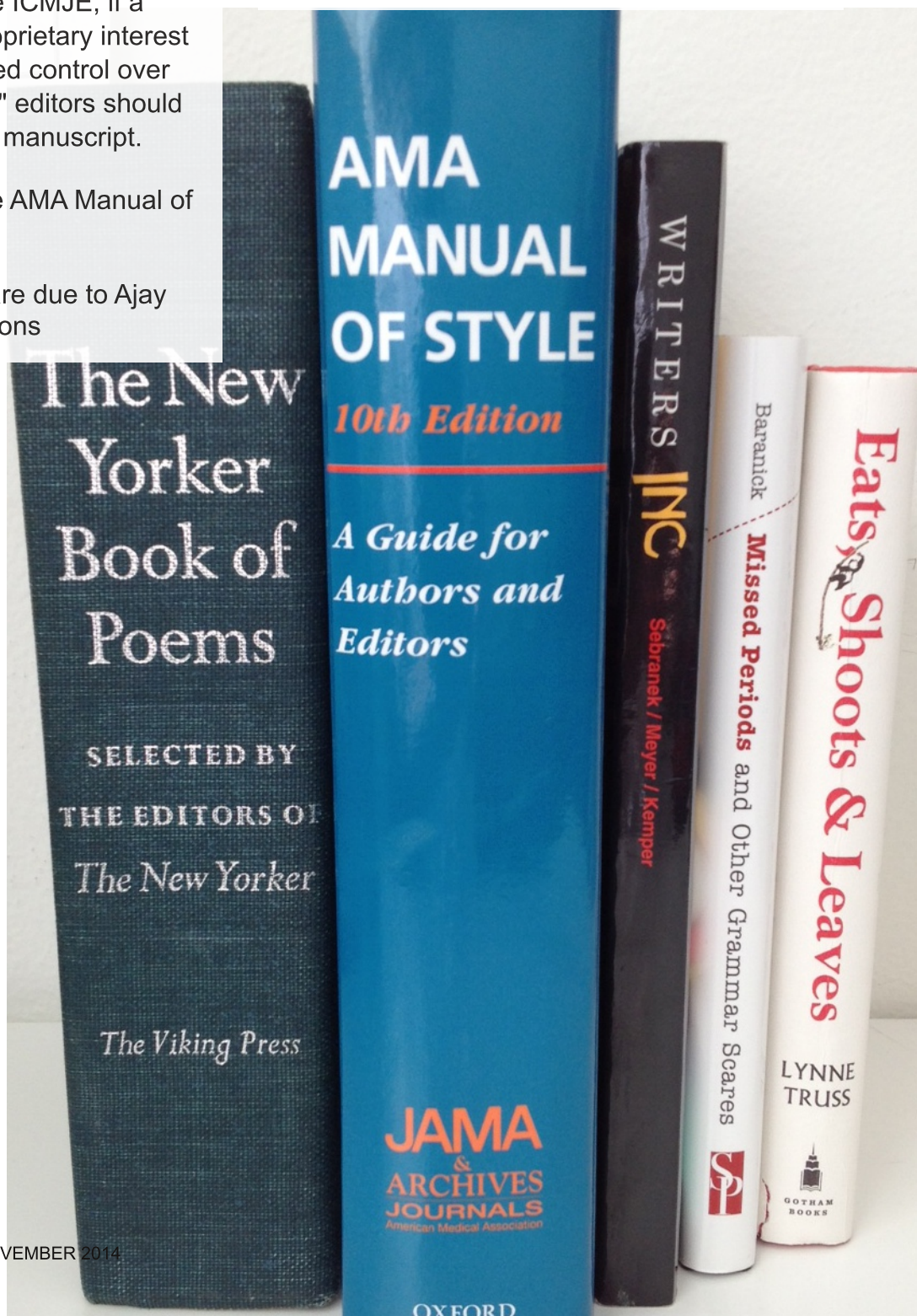
the study; collection, management, analysis, and interpretation of the data; and preparation, review, or approval of the manuscript." If the sponsor or funder had no such role, this should be stated. This information may be included in the Methods or Acknowledgment sections of the manuscript. Authors should not agree to allow sponsors with a proprietary or financial interest in the outcome of a study or review article to control the author's rights to publication. According to the ICMJE, if a sponsor or funder with a proprietary interest in a manuscript has "asserted control over the authors' right to publish," editors should decline consideration of the manuscript.

Also see pages 168-179 of the AMA Manual of Style 10th edition.

Acknowledgement: Thanks are due to Ajay Malik, PhD, for useful discussions

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2. AMA Advocacy Topics. Physician Financial Transparency Reports (Sunshine Act) <http://www.ama-assn.org/ama/pub/advocacy/topics/sunshine-act-and-physician-financial-transparency-reports.page>. Accessed Oct 20, 2014.





SAVE THE DATE!

2015 AMWA Pac-SW Conference
May 1 – May 2, 2015

Courtyard Marriott San Diego, Old Town
2435 Jefferson St, San Diego 92110
www.oldtownsandiegoguide.com

Join us for small-group workshops, networking opportunities and provocative conversations with writers, editors, scientists, and other medical communicators in fun-filled and historic Old Town, home to numerous food, shopping, entertainment and cultural venues.

Here's a taste of the open sessions:

- Preparing a Clinical Study Report
- Setting up a Freelance Business
- Using Storytelling Skills to Tailor Communications for Different Audiences
- Medical communications careers (panel discussion)



Plus 2 Workshops!

- Outlining for Writers and Editors (ES/EW/FL) [2007], Sue Hudson
- Effective Paragraphing (ES/G) [2003], Helen Hodgson

☀ 2015 PACIFIC-SOUTHWEST CONFERENCE AWARD ☀

Established to support ongoing education of medical writers, the award recipient will receive free conference registration. All current/aspiring medical writers are welcome to submit an entry. Information and entry form coming soon!

REGISTRATION OPENS JANUARY 2015!



What's Up(?) . . . at FDA

By Amanda Fisher, PhD

During the end of September and the month of October the FDA announced a flurry of legal actions, voluntary recalls, and draft guidances. Hospira's troubles continued this month with recalls of Vancomycin, Lidocaine and a number of intravenous solutions. In addition, the FDA approved new drugs with the following indications: Circadian rhythm sleep disorder, nausea associated with chemotherapy treatment, and hepatitis C. The agency also approved two drugs to treat idiopathic pulmonary fibrosis. To address the current Ebola outbreak the FDA has authorized the emergency use of BioFire Defense diagnostic tests. These tests allow certain hospitals to conduct in-house PCR tests for Ebola.¹

Selected FDA Announcements

| Date | Announcement |
|----------|--|
| 9-25-14 | U.S. Marshals raided Rosefield Management, Inc. (Van Nuys, CA) and seized 25,000 lbs of Kratom leaves. Kratom is a plant from southeast Asia with opiate-like properties. ² The leaves were purportedly being sold by Wholesale Shamanic Herbs with claims that consumption of the leaves could cure or mitigate disease. ³ |
| 10-3-14 | Sagent Pharmaceuticals issued a voluntary recall of Ketorolac Tromethamine Injection, USP, 30mg/mL single-dose vials due to incorrect expiration dates. ⁴ |
| 10-6-14 | The FDA released a final guidance for industry titled "Pathologic Complete Response in Neoadjuvant Treatment of High-Risk Early-Stage Breast Cancer: Use as an Endpoint to Support Accelerated Approval." The guidance provides assistance in the design of appropriate trials for applicants seeking approval of drugs and medical devices for the treatment of breast cancer in a preoperative setting. ⁵ |
| 10-7-14 | The FDA released a draft guidance on "Over-the-Counter Pediatric Liquid Drug Products Containing Acetaminophen." ⁶ |
| 10-7-14 | Hospira issued a voluntary recall of Vancomycin Hydrochloride for Injection, USP, Equivalent to 1 g Vancomycin (Sterile Powder) because of potential exposure to unsafe temperatures during transit. ⁷ |
| 10-10-14 | The FDA released a final guidance for industry on "New Chemical Entity Exclusivity Determinations for Certain Fixed-Combination Drug Products." The guidance is part of the agency's incentivization of the development of fixed-combination products. ⁸ |
| 10-14-14 | A federal judge in Ohio entered a consent decree for a permanent injunction against Ascend Laboratories, LLC (Montvale, New Jersey) on behalf of the FDA. The decree requires Ascend to post bond for the release of their unapproved prescription drugs before they can complete a court-ordered destruction of the drugs. In May, 2014 U.S. Marshals seized unapproved drugs from Ascend, including Pramoxine-HC Otic Drops; Hydrocortisone Acetate Suppositories 25 milligrams; Urea Cream 39%; Urea Cream 40%; and Urea Lotion 40%. ⁹ |
| 10-14-14 | Hospira issued a voluntary recall of a number of intravenous solutions sold under the brand name LifeCare because an inspection revealed a leaky container, creating the potential for contamination. ¹⁰ |
| 10-17-14 | Hospira issued a voluntary recall of 1% Lidocaine HCl for Injection, USP, 10 mg per mL, 30 mL Single-dose, Preservative-Free because of the presence of human hair embedded in the stopper. ¹¹ |
| 10-21-14 | The FDA released a draft guidance for industry "Migraine: Developing Drugs for Acute Treatment." ¹² |

Selected FDA Approvals

| Drug | Indication | Company |
|----------------------|---|----------------------|
| Hetlioz [®] | Non-24-hour sleep-wake disorder ¹³ | Vanda |
| Lumason [™] | Opacifies the left ventricular chamber in patients with sub-optimal echocardiograms ¹⁴ | Bracco |
| Akynzeo [®] | Nausea and vomiting associated with cancer chemotherapy ¹⁵ | Helsinn |
| Harvoni [®] | Chronic hepatitis C virus genotype 1 infection ¹⁶ | Gilead |
| Esbriet [®] | Idiopathic pulmonary fibrosis ¹⁷ | InterMune |
| Ofev [®] | Idiopathic pulmonary fibrosis ¹⁸ | Boehringer Ingelheim |

November 2014 Advisory Committee Meetings

| Date | Committee |
|-------------|--|
| 11-6-14 | Oncologic Drugs Advisory Committee - NDAs submitted by Novartis and Rockwell Medical ¹⁹ |
| 11-6-14 | Cellular, Tissue and Gene Therapies Advisory Committee- Discussion of a draft guidance for industry, "Design and Analysis of Shedding Studies for Virus or Bacteria-Based Gene Therapy and Oncolytic Products" ²⁰ |
| 11-18-14 | Drug Safety and Risk Management Advisory Committee- Discussion of risk management of eculizumab injection (Alexion Pharmaceuticals) ²¹ |
| 11-24/25-14 | Anesthetic and Analgesic Drug Products Advisory Committee- Discussion of the risk of neurologic adverse reactions associated with epidural steroid injections administered for pain management ²² |

November 2014 Meetings, Conferences, and Workshops

| Date | Title |
|-----------|--|
| 11-4/6-14 | Clinical Investigator Training Course, College Park, MD ²³ |
| 11-18-14 | FDA Outreach to the Pediatric Cancer Advocacy Community, Silver Spring, MD ²⁴ |

WEBLINKS

- For additional information on approvals, including labeling revisions, tentative approvals, efficacy supplements with supporting clinical data, manufacturing changes or additions, or chemistry; new strength, see <http://www.fda.gov/NewsEvents/Newsroom/default.htm> [Link]
- For additional information on recalls, market withdrawals, and safety alerts, see <http://www.fda.gov/Safety/Recalls/default.htm> [Link]
- For information on current drug shortages, see <http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050792.htm> [Link]
- For information on drugs to be discontinued, see <http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050794.htm> [Link]
- For Orange Book drug product list additions or deletions, see <http://www.fda.gov/Drugs/InformationOnDrugs/ucm086229.htm> [Link]

¹ <http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/ucm410308.htm> [Link]

² http://www.deadiversion.usdoj.gov/drug_chem_info/kratom.pdf [Link]

³ <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm416318.htm> [Link]

⁴ <http://www.fda.gov/Safety/Recalls/ucm417357.htm> [Link]

⁵ <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM305501.pdf> [Link]

⁶ <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM417568.pdf> [Link]

⁷ <http://www.fda.gov/Safety/Recalls/ucm418028.htm> [Link]

⁸ <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM386685.pdf> [Link]

⁹ <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm418867.htm> [Link]

¹⁰ <http://www.fda.gov/Safety/Recalls/ucm418879.htm> [Link]

- ¹¹ <http://www.fda.gov/Safety/Recalls/ucm419308.htm> [Link]
- ¹² <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM419465.pdf> [Link]
- ¹³ http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/205677s000lbl.pdf [Link]
- ¹⁴ http://www.accessdata.fda.gov/drugsatfda_docs/applletter/2014/203684Orig1s000ltr.pdf [Link]
- ¹⁵ <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm418375.htm> [Link]
- ¹⁶ <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm418365.htm> [Link]
- ¹⁷ <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm418991.htm> [Link]
- ¹⁸ <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm418994.htm> [Link]
- ¹⁹ <http://www.fda.gov/AdvisoryCommittees/Calendar/ucm418352.htm> [Link]
- ²⁰ <http://www.fda.gov/AdvisoryCommittees/Calendar/ucm411073.htm> [Link]
- ²¹ <http://www.fda.gov/AdvisoryCommittees/Calendar/ucm417986.htm> [Link]
- ²² <http://www.fda.gov/AdvisoryCommittees/Calendar/ucm417300.htm> [Link]
- ²³ <http://www.fda.gov/Drugs/NewsEvents/ucm404034.htm> [Link]
- ²⁴ <http://www.fda.gov/Drugs/NewsEvents/ucm419808.htm> [Link]



Quest toward Brilliance

Save The Date for **AMWA's 75th Annual Conference,**
September 30 - October 3, 2015, in San Antonio, TX

Grand Hyatt San Antonio

600 E Market Street, San Antonio, TX 78205

What's Up(!) . . . at EMA

By Wim D'Haeze, PhD

EUROPEAN MEDICINES AGENCY (EMA) ALERTS (27 SEP 2014 THROUGH 26 OCT 2014)

The alerts listed below cover the period from September 27, 2014 through October 26, 2014. Only key alerts thought to be of interest to the AMWA community were included; for additional updates and details refer to What's New on the EMA website.

GUIDELINES

- None to report

REPORTS/PAPERS

- None to report

APPROVALS/REFUSALS

| Compound | Indication/Use ¹ | Applicant | Advice [Note] |
|-----------------------------------|--|--------------------------------|------------------|
| Duavive ^a | Treatment of oestrogen deficiency symptoms in postmenopausal women with a uterus (with at least 12 months since the last menses) for whom treatment with progestin-containing therapy is not appropriate. | Pfizer Ltd. | Positive opinion |
| Duloxetine Lilly ^b | Treatment of major depressive disorder, diabetic peripheral neuropathic pain, and generalised anxiety disorder in adults. | Eli Lilly Nederland B.V. | Positive opinion |
| Paliperidone Janssen ^c | Maintenance treatment of schizophrenia in adult patients stabilised with paliperidone or risperidone. In selected adult patients with schizophrenia and previous responsiveness to oral paliperidone or risperidone, Paliperidone Janssen may be used without prior stabilisation with oral treatment if psychotic symptoms are mild to moderate and a long-acting injectable treatment is needed. | Janssen-Cilag International NV | Positive opinion |
| Scenesse ^d | Prevention of phototoxicity in adult patients with erythropoietic protoporphyria (EPP) | Clinuvel UK Ltd. | Positive opinion |
| Lynparza ^e | Monotherapy for the maintenance treatment of adult patients with platinum-sensitive relapsed BRCA-mutated (germline and/or somatic) high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete response or partial response) to platinum-based chemotherapy. | AstraZeneca AB | Positive opinion |

| | | | |
|----------------------|--|-------------------------|------------------|
| Rixubis ^f | Treatment and prophylaxis of bleeding in patients (all age groups) with haemophilia B (congenital factor IX deficiency). | Baxter Innovations GmbH | Positive opinion |
|----------------------|--|-------------------------|------------------|

1. As per recommended approval

Note: "positive" or "negative" opinion indicates the Committee for Medicinal Products for Human Use (CHMP) adopted a positive or negative opinion in regards of granting the marketing authorization, respectively, awaiting a final decision of the European Commission (EC).

GENERAL ANNOUNCEMENTS

- EMA ready to start assessment of Ebola vaccines and treatments as soon as data are made available.⁹

WEBLINKS

EMA Website - What's New:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/landing/whats_new.jsp&mid=WC0b01ac058004d5c4 [Link]

a.http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002314/smops/Positive/human_smo_p_000743.jsp&mid=WC0b01ac058001d127 [Link]

b.http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004000/smops/Positive/human_smo_p_000745.jsp&mid=WC0b01ac058001d127 [Link]

c.http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004066/smops/Positive/human_smo_p_000746.jsp&mid=WC0b01ac058001d127 [Link]

d.http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002548/smops/Positive/human_smo_p_000747.jsp&mid=WC0b01ac058001d127 [Link]

e.http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003726/smops/Positive/human_smo_p_000744.jsp&mid=WC0b01ac058001d127 [Link]

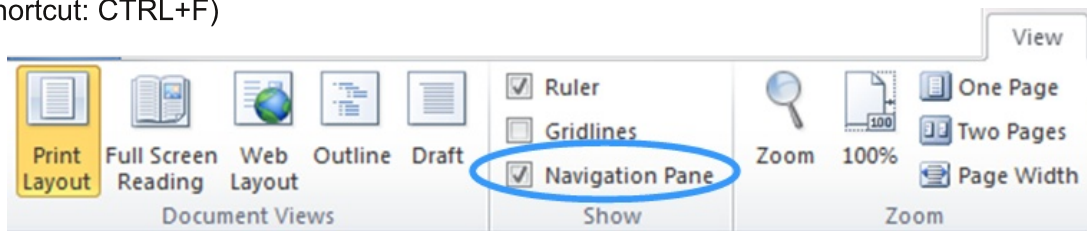
f.http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003771/smops/Positive/human_smo_p_000748.jsp&mid=WC0b01ac058001d127 [Link]

g.http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2014/10/news_detail_002192.jsp&mid=WC0b01ac058004d5c1 [Link]

de-MS-tifying Word: Navigating the Navigation Pane

By Susan Chang, PhD, Susan Chang Consulting

One of my favorite features of MS Word 2010 is the Navigation Pane (previously called the Document Map). Its increased functionality has cut down my document prep time significantly! To open the Navigation Pane, go to **View** tab → **Show** group → check **Navigation Pane** (or shortcut: CTRL+F)



The Navigation Pane will open on the left-hand side. If your text has heading level styles applied, they will be listed in the Navigation Pane in an outline format. Simply clicking on a heading takes you to that place in the document!

TIP: If you see a blank space in the Navigation Pane, something is formatted incorrectly!

The two main “buckets” for Navigation Pane features are Section options and Find options:

SECTION OPTIONS

You can manage large sections of text easily using the Navigation Pane.

To move sections within your document, just click on the section heading, then drag and drop it to another location within the Navigation Pane. There's no easier way to rearrange a document!

Other section-related features are available if you right-click on the section name. I have found this most useful for deleting an entire section and for copying an entire section.

To delete an entire section, right-click on the section heading within the Navigation Pane and choose “Delete.”

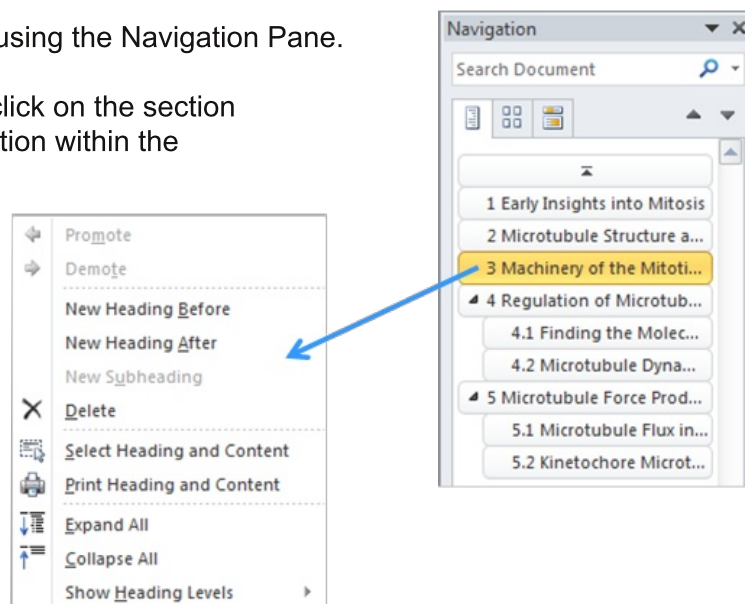
To copy/paste an entire section, right-click on the section heading and choose “Select heading and content.” Then copy (CTRL+C) and paste (CTRL+V) in your new destination for this section.

NOTE: Everything within the section will be affected, so make sure your text, figures, and tables are formatted properly!

FIND OPTIONS

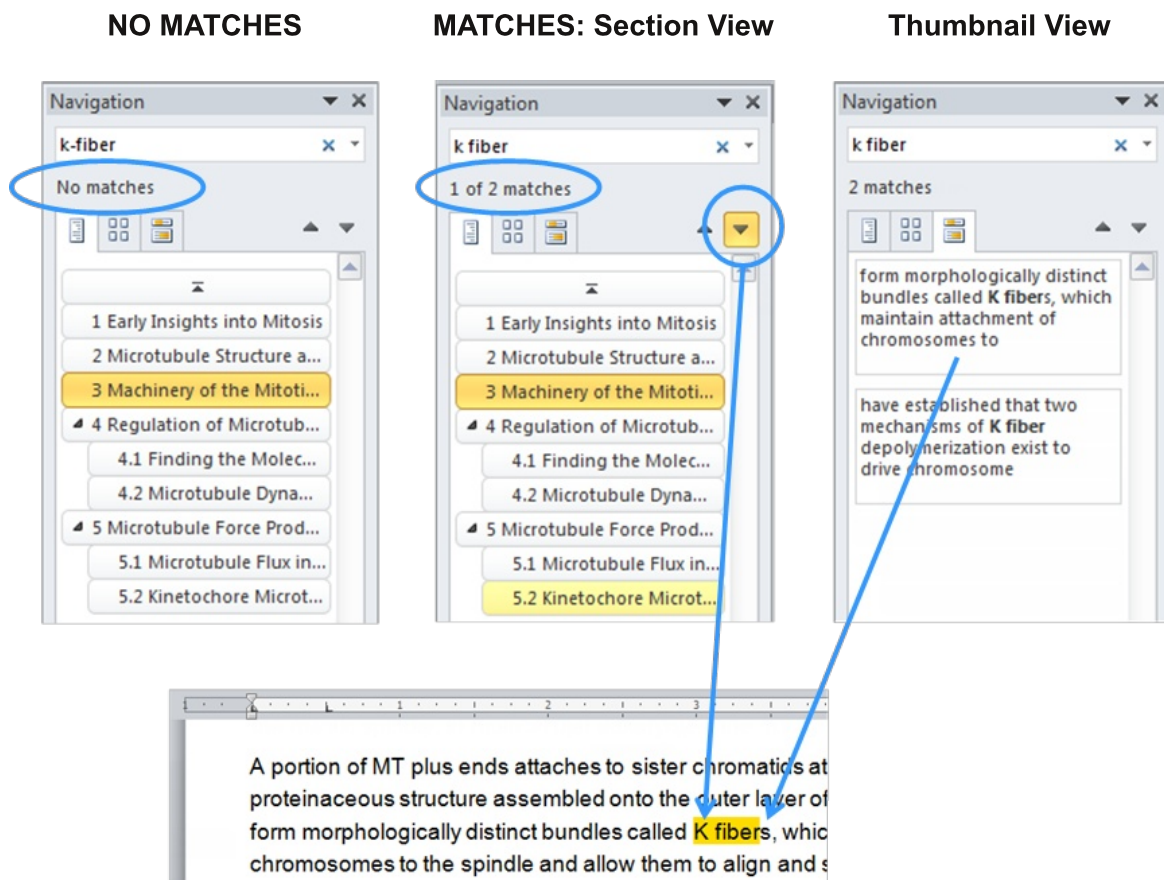
Perhaps the most useful features in the Navigation Pane are the “find” options. Just type your word or phrase of interest in the search window at the top of the Navigation Pane and hit enter. (Shortcut: highlight the text of interest and hit CTRL+F).

If nothing in the document matches your search, “No matches” will appear.



If your term is present in the document, several things will happen:

- The Navigation Pane will show you the total number of matches. You can click on the up or down arrows just below the search window to jump from match to match.
- Within the document itself, the matching term will be highlighted yellow. This highlight is temporary; it only appears when a matching term is typed into the Navigation Pane search window.
- Within the Navigation Pane, there are several tab options:
 - o Left tab – Sections containing a match will be highlighted light yellow, and the section that you're currently in will be highlighted darker yellow.
 - o Center tab – Pages with matches will be highlighted.
 - o Right tab – Thumbnail views of the matching term within the context of the document will be shown. Click on any thumbnail to go directly to this location!



You may be thinking, so what? Well, this is what (ie, these are the awesome things you can do with the find function, especially using the thumbnail view):

- Quickly check hyphenation, capitalization, and other style options
- Quickly cross-check consistency of revisions, reference list versus in-text citations, abbreviations versus definitions, and much more!

If you need to narrow the number of matches to something more manageable, you can define additional search criteria using the drop-down arrow to the right of the Navigation Pane search window. Happy hunting!

Word woes? Email me at SKC@SusanChangConsulting.com.

AMWA Pac-SW Presenters — Thanks!

Albert Y. Rhee, PhD, Amgen Inc., Thousand Oaks, CA

- Scientific Congress Coverage for a Pharmaceutical/Biotechnology Company

April A. Reynolds, Write/Correct, Inc., San Diego, CA (co-presenter)

- Hands On: Can Google Hangout On Air

Cynthia Carr, PhD, Ventana Medical Systems, Inc, Tuscon, AZ (co-presenter)

- FDA's Other Box: Medical Device Regulation for Pharmaceutical Writers

Denise L. Sturrock, MPH, Abbott Medical Optics Inc, Santa Ana, CA

- Dot Your Eyes, Don't Cross Them: Ophthalmology from a Medical Writer's Perspective

Jane Neff Rollins, MSPH, Arnell Communications; Montrose, CA

- Basics of Epidemiology

Jennifer Grodberg, PhD, RAC, AMWA-PacSW past-president (co-presenter)

- Scope of Medical Communication
- Investigational New Drug Applications

Jenilyn J. Virrey, PhD, CMPP, Amgen Inc., Thousand Oaks, CA

- How to Network: a Systematic, Hands-on Approach

Julie R. L. Wang, DPM, Amgen Inc., Thousand Oaks, CA

- Standard Operating Procedures for Clinical Scientific Publications

Kathy Boltz, PhD, Freelance Medical Writer, Phoenix, AZ

- From Academic Scientist to Freelance Writer: Sharing Lessons Learned

Kathryn Boorer, PhD, Amgen Inc., Thousand Oaks, CA

- Developing Publications in Accordance with GPP2 Guidelines

Lori M. Smette, PhD, Amgen, Inc., Thousand Oaks, CA

- Demonstrating Leadership When You're Not the Leader

MaryAnn Foote, PhD, MA, Foote Associates, Westlake Village, CA

- Critical Appraisal for Writers and Editors of Biomedical Research Articles

Michael Lewis Schneir, MS, PhD, Professor, Ostrow School of Dentistry of Univ of Southern California, Los Angeles, CA

- Sentence Structure and Patterns

continued on next page. . .

Rachel Meyer, Director of Creative Content & SEO Analyst, Medical Marketing Solutions, Mesa, AZ

- Hands On: Advanced Google Techniques for Content Creation/Curation
- Hands On: Applied Search Engine Optimization (SEO) for the Medical Writer
- Keep Your Record Clean while Running a Great Social Media Campaign

Scott Harrington, PharmD, RPh, Tucson, AZ

- When it's Time to Blow the Whistle: Writers' Power in Challenging Ethically Compromising Situations

Sherree Geyer, Managing Partner, QuickSilver Edge, LLC, Lake Forest, CA

- How To: Champagne Results on a beer budget—High-end Health Care Public Relations for Less

Tim Peoples, MA, ELS, CMPP, Amgen Inc, Thousand Oaks, CA (co-presenter)

- FDA's Other Box: Medical Device Regulation for Pharmaceutical Writers

Yeshi Mikyias, PhD, ELS, Baxter Healthcare, Thousand Oaks, CA (co-presenter)

- Writing Abstracts
- Regulatory Aspects of the Drug Development
- POSTER: Successfully Onboarding a Medical Writer: Filling the Gap between Orientation and Integration

Tom Gegeny, MS, ELS; Marianne Mallia, ELS; David Clemow, PhD; James Cozzarin, ELS; Barbara Gastel, MD, MPH; Bart Harvey, MD, PhD; **Sue Hudson**, and Karen Klein, MA, ELS; on behalf of the 2013–2014 Medical Writing Certification Commission

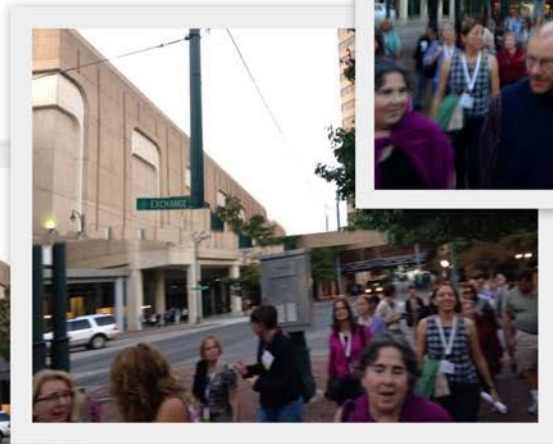
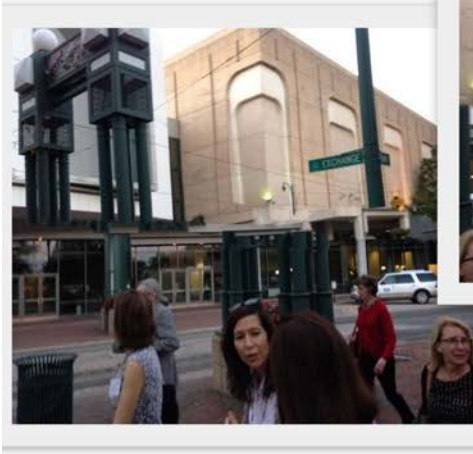
- POSTER: Getting Ready for the AMWA Medical Writing certification examination

ANNUAL CONFERENCE COMMITTEE ADMINISTRATOR ELECT: **Noelle**

Demas, MS, Past-President, AMWA PacSW; Panorama MedWriters Group, Inc, San Diego, CA

AMWA Pac-SW Members "Meet & Greet" Outing in Memphis

Walking through downtown.



The Banner says it all: "Laissez les bons temps rouler!" — is a Cajun expression meaning "Let the good times roll!"

Studying the menu, and overfilling the room!



Pictures by Donna Simcoe. Collage and text by Ajay Malik.

About 45 members from our Chapter attended AMWA's 74th Annual Conference in Memphis, TN, and most joined for a walk to the neighborhood restaurant, DeJAVU, for authentic New Orleans cuisine.

Images from Memphis

By Kathy Boltz



Pictures by Kathy Boltz. Collage by Ajay Malik.

Kathy Boltz took time off from the AMWA meeting in Memphis to enjoy the history, sight and sound of Memphis, and shared these pictures: Peobody Hotel (center) is famous for their ducks that live in their fountain and get to waddle down the red carpet and ride the elevator to their penthouse suite at 5 PM daily—a kid's favorite event. Lorraine Motel (bottom right) is where ML King was shot; it's now the National Civil Rights Museum. See the cover page for the epicenter of the Memphis music scene, Beale St at night. Eskimo Bros. playing honky-tonk/rockabilly in Blues City Cafe (top left and right), and yes, Kathy saw him playing his guitar behind his back, Wow! And, also playing in the Blues City Cafe was Earl "The Pearl" Banks playing the blues (bottom).

—Editor